Idera Pharmaceuticals Announces Favorable Data from Phase 1b Study of IMO-2055 in Combination with Tarceva(R) and Avastin(R) in Patients with Advanced Non-Small Cell Lung Cancer

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CAMBRIDGE, Mass., Jan 20, 2012 (BUSINESS WIRE) --Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) today announced favorable safety and efficacy results from a Phase 1b study of IMO-2055, a TLR9 agonist, in combination with Tarceva(R) and Avastin(R) in thirty-six patients with advanced non-small cell lung cancer (NSCLC) who have previously failed one or more prior therapies. In this trial, the combination of IMO-2055 with Tarceva and Avastin was well tolerated. Thirty-three patients were evaluable for efficacy, and showed a disease control rate of 79%, a median progression-free survival of 5.6 months and a median overall survival of 16 months.

"These results compare favorably with the recently published results of the BeTa trial of Avastin and Tarceva in second line treatment of patients with advanced NSCLC," commented David Smith, M.D., of US Oncology and a Principal Investigator on the Phase 1b trial. "We identified a recommended dose of IMO-2055 with standard doses of Tarceva and Avastin. Additional exploration of safety and efficacy from this trial suggests that IMO-2055 should be further investigated in NSCLC."

"We are very encouraged with the results of this clinical trial in heavily pre-treated patients with NSCLC, which is a difficult-to-treat disease with poor prognosis," said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer of Idera. "These data support the development of IMO-2055 as an immune modifier to potentiate the anticancer activity of biologically targeted agents. The results from the current NSCLC trial and the data anticipated from an ongoing Phase 2 trial of IMO-2055 in combination with Erbitux(R) in patients with head and neck cancer will inform our decisions on the next steps in development of IMO-2055."

The Phase 1b clinical trial in NSCLC evaluated four dose levels of IMO-2055 in combination with standard doses of Tarceva and Avastin. Patients received oral Tarceva at 150 mg once per day and Avastin at 15 mg/kg once every three weeks by intravenous infusion in addition to subcutaneous doses of IMO-2055 once per week until disease progression or other discontinuation criteria was met. The trial enrolled 36 patients who had failed at least one prior course of chemotherapy. The trial was conducted at 10 centers in the United States. Nineteen patients were recruited to the dose-escalation portion of the trial, in which 0.32 mg/kg was identified as the recommended Phase 2 dosage of IMO-2055. An additional 17 patients were recruited and treated at 0.32 mg/kg/week to further document safety and efficacy.

The study population was typical for a second- to fifth-line treatment population in a Phase 1 study. No new or unexpected toxicities were observed in the study, and rates of well-known side effects of the three agents were consistent with results from previously presented clinical trials of IMO-2055 and of the combination of Tarceva and Avastin. The most common adverse events were diarrhea, nausea, fatigue and rash.

Idera plans to present the detailed results at an upcoming scientific meeting.

About IMO-2055

IMO-2055 is a novel proprietary agonist of TLR9 and induces innate and adaptive immune responses. IMO-2055 is being developed as an immune modifier to potentiate the anticancer activity of biologically targeted agents. Preclinical studies have shown increased anti-tumor activity when IMO-2055 is combined with targeted anticancer agents including Tarceva, Avastin, and Erbitux. In addition to the Phase 1b study referred to in this release, a Phase 1b study of IMO-2055 in combination with Erbitux and FOLFIRI in patients with colorectal cancer has been completed and data analysis currently is ongoing. A Phase 2 study of IMO-2055 in combination with Erbitux in patients with squamous cell carcinoma of the head and neck is fully recruited, and patient treatment and follow-up are ongoing. Merck KGaA, Darmstadt, Germany, conducted these trials. In November 2011, Idera regained all rights to IMO-2055 from Merck KGaA.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals applies its proprietary Toll-like Receptor (TLR) drug discovery platform to create immunomodulatory drug candidates. The Company's TLR-targeted candidates are being developed to treat autoimmune and inflammatory diseases and cancer, and for use as vaccine adjuvants. Additionally, the Company is advancing its gene-silencing oligonucleotide (GSO) technology for the purpose of inhibiting the expression of disease-promoting genes. For more information, visit http://www.iderapharma.com.

Idera Forward Looking Statements

This press release contains forward-looking statements concerning Idera Pharmaceuticals, Inc. that involve a number of risks and uncertainties. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "should," "could," "will," "may," and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated by such forward-looking statements, including whether early clinical results such as the results described in this release will be indicative of results obtained in later clinical trials; whether products based on Idera's technology will advance into or through the clinical trial process on a timely basis or at all and receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; whether the Company's collaborations will be successful; whether Idera's cash resources will be sufficient to fund the Company's operations; and such other important factors as are set forth under the caption "Risk Factors" in Idera's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011 which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

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